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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/758,357	01/15/2004	Shalaby W. Shalaby	SHA-49	5302

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EXAMINER

ROGERS, JAMES WILLIAM

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 07/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/758,357	Applicant(s) SHALABY, SHALABY W.	
	Examiner James W. Rogers, Ph.D.	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 2,3 and 6-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,5 and 10-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>05/10/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of group II, claims 1,4,5 and 10-14 in the reply filed on 06/15/2006 is acknowledged.

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1,4-5,13 and 14 rejected under 35 U.S.C. 102(e) as being anticipated by Sawhney (US 6,818,018).

Sawhney teaches injectable in situ polymerizable hydrogels that can be absorbable or non-absorbable by appropriate structural design of the hydrogel forming precursors. See abstr, col 4 lin 53-55, col 18 lin 50-col 19 lin 21. It is noted by the examiner that most of the Sawhney patent discloses water soluble hydrogel compositions but since it is within the scope of the patent that the hydrogel can be non-absorbable it is inherent that the skilled artisan would a greater concentration of hydrophilic polymers such as polyethers to form non-absorbable hydrogel compositions. Regarding the limitations in claim 4 that the polymeric composition comprises a liquid succinic anhydride-bearing polymer and liquid diamine capable of an in situ reaction to form a crosslinked network is met because Sawhney teaches that the polymer can comprise various hydrophobic polyethers which can then comprise either a nucleophile

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(including hydrazine and diamines) or/and an electrophile (including succinic anhydrides such as malaic anhydride), the electrophilic groups and nucleophilic groups being reactive towards one another and forming a cross-linked network. See col 11 lin 22-56 and col 13 lin 52-col 15 lin 16. The limitation in claim 5 fails to further limit claim 4 because this is a product by process claim and “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Regarding claim 13 the limitation that the injectable polymeric composition further comprises a cell-growth promoting agent is met because Sawheny teaches that the hydrogels can contain biologically active agents that can promote hard or soft tissue growth (including fibronectin, hydroxyapatite, tricalcium phosphate, ect). See col 17 lin 53-65. Regarding claim 14 it is deemed inherent by the examiner that any hydrogel composition for use as an injectable for a patient would be sterilized before use in the body of a patient therefore this limitation was given no patentable weight by the examiner.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1,4-5 and 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sawhney (US 6,818,018) in view of Trieu (US 20020026244 A1).

Sawhney is disclosed above.

The Sawhney patent discloses applications for the hydrophilic hydrogel including spinal implants, bone prostheses and augmenting bone fractures but does not reasonably disclose its use as a precursor for the treatment of a herniated disc or a precursor for a prosthetic intervertebral disc nucleus pulposus.

The Trieu patent is used to primarily show that the use of hydrogels for intervertebral disc nucleus implants was well known in the art at the time of the invention. See abstract, [0004], [0060]. Regarding claim 12 it is obvious that the nucleus pulposus implants can be used for the treatment of herniated disc since they are provided for the treatment of the nucleus pulposus protruding into the vertebral canal, the same symptom as a herniated disc.

It would have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to combine the art described in the documents above because Sawhney discloses all of applicants claimed invention but is silent on the use of the hydrogels as a precursor for the treatment of a herniated disc or a precursor for a prosthetic intervertebral disc nucleus pulposus, while the Trieu patent was used to show that the use of hydrogels for nucleus pulposus implants was well known at the time of the invention. The motivation to combine the above documents would be a non-

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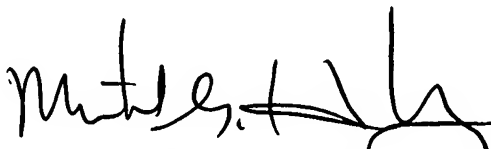
absorbable hydrogel that can be used as prosthetic intervertebral disc nucleus pulposus for the treatment of a herniated disc. Thus, the claimed invention, taken as a whole was *prima facie* obvious over the combined teachings of the prior art.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER